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10/525,193	08/12/2005	Peter Gingras	14188-003US1	3946

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EXAMINER	
SIMPSON, SARAH A	
ART UNIT	PAPER NUMBER
3731	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/525,193	GINGRAS, PETER	
	Examiner	Art Unit	
	SARAH A. SIMPSON	3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 February 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-31* is/are pending in the application.

4a) Of the above claim(s) *15-18 and 20-22* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-14,19 and 23-31* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *22 February 2005* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *7/26/2007;5/16/2005;2/22/2005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-14, 19 and 23-31, drawn to an implant classified in class 606, subclass 151.

Group II, claim(s) 15, 16 and 22, drawn to a method of producing the implant classified in class 623, subclass 11.1.

Group III, claim(s) 17, 18, 20 and 21, drawn to a method of repairing a defective tissue classified in class 128, subclass 898.

2. The inventions listed as Groups I, II and III do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: The special technical feature of Group I, a subassembly that resists compression when implanted in a warm-blooded animal is not shared by Group II and III. The special technical feature of Group II, a process to produce a three-dimensional biocompatible implant, is not shared by Group I and III. The special technical feature of Group III, a method for

repairing defective tissue in a patient is not shared by Group I and II. Therefore, the respective groups lack the same or corresponding features and do not relate to a single general inventive concept.

3. Restriction for examination purposes as indicated is proper because all these inventions listed in this action are independent or distinct for the reasons given above and there would be a serious search and examination burden if restriction were not required because one or more of the following reasons apply:

(a) the inventions have acquired a separate status in the art in view of their different classification;

(b) the inventions have acquired a separate status in the art due to their recognized divergent subject matter;

(c) the inventions require a different field of search (for example, searching different classes/subclasses or electronic resources, or employing different search queries);

(d) the prior art applicable to one invention would not likely be applicable to another invention;

(e) the inventions are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a invention to be examined even though the requirement may be traversed (37 CFR 1.143) **and (ii) identification of the claims encompassing the elected invention**.

The election of an invention may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected invention.

If claims are added after the election, applicant must indicate which of these claims are readable upon the elected invention.

Should applicant traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

4. During a telephone conversation with Lee Crews on August 26, 2008 a provisional election was made without traverse to prosecute the invention of Group I, claims 1-14, 19 and 23-31. Affirmation of this election must be made by applicant in replying to this Office action. Claims 15-18 and 20-22 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

5. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Drawings

6. The drawing/photograph disclosure is objected to. Figures 1-3 appear to be photographs which are generally not permitted in utility patent applications. The subject matter of the application admits illustration by a drawing; therefore, the examiner requires a drawing in place of the photographs. MPEP 37 CFR 1.84(b).

The drawings are objected to because the lines, numbers and letters are not uniformly thick and well defined (37 CFR 1.84(i)) and the figure legends are poor (37 CFR 1.84(p).

Corrected drawing sheets in compliance with 37 CFR 1.121 (d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner,

the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Objections

7. **Claims 12, 14, 25 and 26** are objected to because of the following informalities: Claims 12 and 14 are missing periods at the end of their sentences. In claim 25, line 1 "claim23" should be replaced with –claim 23--. In claim 26, line 1 "claim25" should be replaced with –claim 25--. Appropriate correction is required.

Claim Rejections - 35 USC § 112

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. **Claims 3-7** are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 3-7 are invalid under 35 USC 112, second paragraph, since a claim which purports to be both machine and process is ambiguous and therefore does not particularly point out and distinctly claim the subject matter of the invention. Ex parte Lyell, 17 USPQ2d 1548 (1990). In that claims 3-7 are directed to the process rather

than the apparatus of claim 1, these claims will not be further treated on the merits thereof.

Claim Rejections - 35 USC § 102

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

11. **Claims 1-8, 12-14 and 19** are rejected under 35 U.S.C. 102(b) as being anticipated by **Flament et al. (US 6,180,848 B1)**.

Regarding claim 1, Flament et al. disclose a three-dimensional biocompatible implant (1), the implant comprising a subassembly that resists compression when implanted in a warm-blooded animal (figs. 2-4).

Regarding claim 2, Flament et al. disclose the implant of claim 1, wherein the subassembly comprises woven or braided fibers (column 2, lines 62-66).

Regarding claims 3-8, Flament et al. disclose the implant may be constructed in a variety of ways and may be films, felts, knits, wovens, crochets, braided materials or combinations thereof (column 2, lines 62-66).

Claims 3-7 are being treated as a product-by-process limitation. Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process. MPEP 2113.

Regarding claim 12, Flament et al. disclose the implant of claim 1, further comprising an onlay ((6); figs. 3-4; column 3, lines 47-53).

Regarding claim 13, Flament et al. disclose the implant of claim 1, further comprising an anchor ((2); figs. 3-4; column 2, lines 15-18).

Regarding claim 14, Flament et al. disclose the implant of claim 1, further comprising a means for stabilizing the implant during placement within a warm-blooded animal (figs. 3-4; column 2, lines 15-18; column 3, lines 47-53).

Regarding claim 19, Flament et al. disclose the implant of claim 1, wherein the implant is sterile (column 2, lines 34-36; column 3, lines 15-16).

12. **Claims 1-9 and 31** are rejected under 35 U.S.C. 102(e) as being anticipated by **Patel et al. (US 6,436,132 B1)**.

Regarding claim 1, Patel et al. disclose a three-dimensional biocompatible implant (10), the implant comprising a subassembly that resists compression when implanted in a warm-blooded animal (column 5, lines 1-6).

Regarding claim 2, Patel et al. disclose the implant of claim 1, wherein the subassembly comprises woven or braided fibers (column 6, lines 1-3).

Regarding claims 3-7, Patel et al. disclose the implant may be constructed in a variety of ways and may be made by weaving, braiding, or knitting filaments about a mandrel (column 6, lines 1-3).

Claims 3-7 are being treated as a product-by-process limitation. Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process. MPEP 2113.

Regarding claims 8 and 9, Patel et al. disclose the implant may be a porous polymer film wherein the pores are 10-100 microns (column 2, lines 19-37).

Regarding claim 31, Patel et al. disclose a three-dimensional implant (10) comprising two or more layers of two- dimensional biocompatible material with interconnecting supports, said implant constructed to securely fit within a tissue or muscle wall defect (column 6, lines 1-25).

Claim Rejections - 35 USC § 103

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

14. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

15. **Claim 10** is rejected under 35 U.S.C. 103(a) as being unpatentable over **Flament et al. (US 6,180,848 B1)** in view of **Rutkow et al. (US 5,356,432)**.

Regarding claim 10, Flament et al. disclose the implant made of a film in a conical form (column 2, lines 19-21, 62-64), but fails to disclose wherein the subassembly comprises pores of 50-2000 microns in diameter.

However, Rutkow et al. teach the implant formed of a biological compatible, flexible and porous surgical mesh fabric suitable for reinforcing tissue and occluding tissue defects (column 1, lines 38-48).

Given the teachings of Rutkow et al., it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the implant of Flament et al. with a porous film in the range of 50-2000 microns. Doing so would reinforce tissue and occlude tissue defects, as disclosed by Rutkow et al. It has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or working ranges involves only routine skill in the art.

16. **Claims 11 and 23-30** are rejected under 35 U.S.C. 103(a) as being unpatentable over **Flament et al. (US 6,180,848 B1)**.

Regarding claims 11 and 25-30, Flament et al. disclose the implant wherein the biocompatible material comprises synthetic or natural materials, including absorbable and nonabsorbable materials such as polytetrafluoroethylene (column 2, lines 32-60).

Flament et al. fail to disclose wherein the implant comprises polyaryletherketone, PGA, PLA, polycaprolactone, polyhydroxylkanoate, or collagen.

However, Flament et al. teach numerous biocompatible synthetic or natural absorbable and nonabsorbable materials can be used for the implant (column 2, lines 32-60).

Given the teachings of Flament et al., it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the implant of Flament et al. with polyaryletherketone, PGA, PLA, polycaprolactone, polyhydroxylkanoate, or collagen. It has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice.

Regarding claims 23 and 24, Flament et al. disclose the implant except for wherein the implant has a surface area to volume ratio less than about 5, 4, 3, 2 or 1.

However, Flament et al. teach from the figures a surface area to volume ratio that appears to be less than about 5, 4, 3, 2 or 1 (figs. 1-4).

Given the teachings of Flament et al., it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the implant of Flament et al. with a surface area to volume ratio of less than about 5, 4, 3, 2 or 1. Doing so would allow for a greater volume of affected tissue to be held open with minimal contact,

reducing tissue irritation. It has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or working ranges involves only routine skill in the art.

Conclusion

17. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SARAH A. SIMPSON whose telephone number is 571-270-3865. The examiner can normally be reached on Monday - Friday 8 am - 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on 571-272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Sarah A Simpson/
Examiner, Art Unit 3731

/Todd E Manahan/
Supervisory Patent Examiner, Art Unit 3731